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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/857,823	06/07/2001	Rolf Ehrhardt	05882.0003.P	2366

27194 7590 11/14/2003

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EXAMINER	
ROARK, JESSICA H	

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 11/14/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/857,823	EHRHARDT ET AL.	
	Examiner	Art Unit	
	Jessica H. Roark	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 August 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *25 and 34-42* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *25 and 34-42* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *07 June 2001* is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

RESPONSE TO APPLICANT'S AMENDMENT

1. The Examiner of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Jessica Roark, Art Unit 1644, Technology 1600.

2. Applicant's amendment, filed 8/22/03, is acknowledged.
Claims canceled: 1-24, 26-33 and 43-44.
Claims amended: 25, 34-36 and 39-42.
Claims pending: 25 and 34-42.

Claims 25 and 34-42 *are under consideration in the instant application.*

3. It is noted that the amendment filed 8/22/03 indicates that claims 1-24, 28-32 and 43-44 are withdrawn. Claims 1-24, 28-32 and 43-44 were cancelled by Applicant in amendments filed 8/30/02 and 1/28/03. The status of these claims should therefore be listed as "cancelled" on any subsequently filed amendment. Failure to correctly indicate the status of the claims in the future will result in a notice of non-compliant amendment.

4. This Office Action will be in response to applicant's arguments, filed 8/22/03
The rejections of record can be found in the previous Office Action (Paper No. 12).

It is noted that New Grounds of Rejection are set forth herein that were not necessitated by Applicant's amendment. Accordingly, this Office Action is Non-Final.

Priority

5. Applicant's claim for domestic priority under 35 U.S.C. 119(e) is acknowledged. However, the provisional application upon which priority is claimed fails to provide adequate support under 35 U.S.C. 112 for claims 36-38 and 40-42 of this application. The Examiner was unable to locate in provisional application 60/111,642 adequate support under 35 USC 112, first paragraph for the specific binding affinity recited in claim 36, the chimeric antibody of claim 37, any of the species of antibodies recited in claim 38, the dosing ranges recited in claims 40-41, and the PASI reduction recited in claim 42. Should the Applicant disagree with the Examiner's factual determination above, it is incumbent upon the Applicant to provide a showing that specifically supports the instant claim limitations.

Claims 36-38 and 40-42 are therefore considered to have an effective filing date of 12/8/1999, the filing date of PCT/US99/29193.

Specification

6. This abstract is objected to because it does not mention the invention to which the claims are directed. Appropriate correction is required..

7. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which Applicant may become aware in the specification.

Claim Rejections - 35 USC § 112 second paragraph

8. The following is a quotation of the second paragraph of 35 U.S.C. 112.

> *The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.*

9. Claim 42 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 42 recites that the treatment reduces PASI by at least 50%. However, neither the specification nor the claims provide a sufficient definition of the metes and bounds of the term "PASI".

Applicant is reminded that any amendment must point to a basis in the specification so as not to add new matter. See MPEP 714.02 and 2163.06.

35 USC § 112 first paragraph

10. In claim 38, it is apparent that the 5F2, 16F2, 16G2 and 20E11 antibodies are required to practice the claimed invention. As a required element, they must be known and readily available to the public or obtainable by a repeatable method set forth in the specification. If they are not so obtainable or available, the enablement requirements of 35 U.S.C. 112, first paragraph, may be satisfied by a deposit of the pertinent hybridomas which produce these antibodies. See 37 CFR 1.801-1.809.

It is noted that page 15 of the specification at lines 26-27 indicates that these antibodies were described in WO 99/37682. Applicant in the Remarks filed 8/22/03 further indicates that U.S. Pat. No. 6,225,117 corresponds to WO99/37682 and recites the cells lines producing these antibodies by their ATCC accession numbers. U.S. Pat. No. 6,225,117 further indicates that the cells lines producing these antibodies were deposited with the ATCC on 12/11/1997 under the terms of the Budapest Treaty. In view of the recitation of the ATCC accession numbers in the claims of an issued U.S. Patent, and Applicant's statement regarding the correspondence of the instantly recited 5F2, 16F2, 16G2 and 20E11 to the antibodies produced by these deposited hybridomas, the enablement requirement under 35 USC 112, first paragraph is considered to be fulfilled.

The rejection of record of claim 38 under 35 USC 112, first paragraph, deposit enablement has therefore been obviated.

35 U.S.C. §§ 102 and 103

11. The following rejections under 35 U.S.C. §§ 102 and 103 are made under the assumption that the effective filing date for claims 36-38 and 40-42 is 12/8/1999; while the effective filing date of claims 25, 34-35 and 39 is 12/9/1998.

Claim Rejections – 35 U.S.C. §§ 102 and 103

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

13. Claims 25, 34-37 and 39-42 are rejected under 35 U.S.C. 102(a) as being anticipated by Strober et al. (WO 98/16248, IDS).

Applicant's arguments, filed 8/22/03, have been fully considered but have not been found convincing. Applicant's arguments are addressed in the context of the revised rejection of record.

Strober et al. teach a method of enhancing oral tolerance to treat an autoimmune disease by administering a monoclonal antibody that binds IL-12 and inhibits its effect, along with an orally administered antigen (see entire document, including claims). Strober et al. specifically teach that an autoimmune disease that can be treated by the administration of an antibody to IL-12 includes psoriasis (see especially claims 11-18 and page 5 at lines 6-21).

Applicant argues that this teaching is not enabling because Strober et al. only mention psoriasis as one of several autoimmune diseases that can be treated, and because the treatment approach taught by Strober et al. requires that an antigen also be administered.

The Examiner acknowledges that Strober et al. teach administration of both an antigen and the antibody to IL-12. However, the instant claim language does not exclude the administration of other active ingredients because the claim language is open (a method comprising the step....). The method taught by Strober et al. comprises the recited step of administering an anti-IL-12 antibody.

It is further noted that Strober et al. specifically contemplate psoriasis as an autoimmune disease that can be treated, as emphasized by the placement of psoriasis in its own dependent claim (claims 8 and 18). Applicant is reminded that a reference that , when the species is clearly named, the species claim is anticipated no matter how many other species are additionally named. *Ex parte A*, 17 USPQ2d 1716 (Bd. Pat. App. & Inter. 1990).

Further, while Applicant has argued that the reference does not place the public in possession of the invention, it is noted that when the reference relied on expressly anticipates or makes obvious all of the elements of the claimed invention, the reference is presumed to be operable. Once such a reference is found, the burden is on applicant to provide facts rebutting the presumption of operability. In re Sasse, 629 F.2d 675, 207 USPQ 107 (CCPA 1980). See also MPEP § 716.07. While Applicant's comments are acknowledged, they do not provide a factual basis for rebutting the presumption of operability with respect to the teachings of Strober et al. in general, or with respect to a method of treating psoriasis in particular.

Strober et al. teach that the anti-IL-12 monoclonal antibody can be humanized (page 7 at lines 1-10).

Strober et al. teach that the antibody is administered either orally or parenterally, and that the dosage can be between 1 and 100 mg/kg body weight (page 9 at lines 14-22). Parenteral administration is taught to include subcutaneous, intramuscular, and intravenous administration (page 9 at lines 2-5).

Reduction of PASI by at least 50% would be inherent in administering an anti-IL-12 antibody to a patient with psoriasis. An antibody that blocks the effect of IL-12 would inherently have an affinity of at least 10^8 M^{-1}.

Applicant is reminded that no more of the reference is required than that it sets forth the substance of the invention. The claimed functional limitations would be inherent properties of administering an antibody to IL-12 for the treatment of psoriasis.

The reference teachings thus anticipate the instant claimed invention.

14. Claims 36-37 and 40-42 are rejected under 35 U.S.C. 102(b) as being anticipated by Strober et al. (WO 98/16248, IDS).

The teachings of Strober et al. have been discussed supra. The rejection set forth above also appears to be applicable to claims 36-37 and 40-42 under 35 USC 102(b) because it does not appear that these claims enjoy adequate written support in priority document 60/111,642 for the reasons set forth supra. Therefore, the rejection set forth supra under 35 USC 102(a) is reiterated herein and applied in the alternative under 35 USC 102(b).

The reference teachings anticipate the instant claimed invention for the reasons set forth supra in the rejection of these claims under 35 USC 102(a).

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> *(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.*

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

16. The previous rejection of claims 25, 34-37 and 39-42 under 35 U.S.C. 103(a) as being unpatentable over US Pat. No. 6,338,848 (of record) in view of Menssen et al. (J. Immunol., 1995; 155:4078-4083, of record) is withdrawn in favor of a New Grounds of rejection.

17. Claims 25, 34-37 and 39-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gillies et al. (WO 96/40093) in view of Leonard et al. (US Pat. No. 6,338,848, of record).

The claims are drawn to methods of treating psoriasis by administering an antibody that binds IL-12 and blocks IL-12 activity.

Gillies et al. teach methods of modulating immune reactions that lead to autoimmune disorders by inhibiting IL-12 (see entire document, e.g., Abstract). Gillies et al. teach methods of identifying compounds which inhibit IL-12 and in turn inhibit IFN-γ production (see entire document). Gillies et al. teach that compounds with this property are useful for treating the autoimmune disease multiple sclerosis and psoriasis (see page 25, first paragraph, in view of the background provided at pages 1-3).

Gillies et al. teach that small molecule inhibitors of IL-12 can be used in combination with other drugs to improve the effectiveness of the treatment (e.g., page 25, first paragraph).

Gillies et al. do not teach that antibodies can be used as antagonists of IL-12.

Leonard et al. teach methods of treating autoimmune diseases by administering antagonists of IL-12 to inhibit IFN-γ production (see entire document, e.g., Abstract). Leonard et al. teach IL-12 antagonists that are monoclonal antibodies that bind IL-12 and inhibit IL-12 activity (column 3 at line 64 to column 4 at line 37). Leonard et al. teach that the monoclonal antibodies to IL-12 can be chimeric (column 4 at lines 1-4) and formulated in pharmaceutical compositions (column 6 at lines 54-67). Leonard et al. teach that the antibodies may be administered via any of a number of routes, including by intravenous or subcutaneous injection (see column 7, especially lines 1-10). Leonard et al. also teach that administration at dosages of 0.05 mg/kg to about 25 mg/kg (see column 7, especially lines 31-34), and that the administration would continue until a meaningful patient benefit is observed by the treatment provider (column 7, lines 10-44).

Leonard et al. teach combining therapies for the treatment of autoimmune conditions (column 7 at lines 39-44).

In view of the teachings of Gillies et al. that psoriasis can be treated using compounds that antagonize IL-12, and the teachings of Leonard that monoclonal antibodies can be used as IL-12 antagonists to treat autoimmune diseases increased by IFN-γ, it would have been obvious to the ordinary artisan at the time the invention was made to treat psoriasis by administering a monoclonal antibody that binds IL-12 and blocks IL-12 activity to a patient with psoriasis. The ordinary artisan at the time the invention was made would have been motivated to combine the anti-IL-12 antibody antagonist of Leonard et al. with the compounds of Gillies et al. because both references teach combining therapies and Gillies et al. note that combining therapies is advantageous to provide a more effective treatment. The ordinary artisan at the time the invention was made would have had a reasonable expectation that the anti-IL-12 antibody antagonist of Leonard et al. could be combined with the antagonists of Gillies et al. to provide a more effective treatment for psoriasis because Gillies et al. teaches the application of IL-12 inhibitors to the treatment of psoriasis and Leonard et al. teach that the antibodies also function as IL-12 inhibitors.

Further, the ordinary artisan would have been motivated to select a monoclonal antibody with an affinity of at least 10^8 M^{-1} in order to have an antibody of sufficient affinity to function as a blocking antibody. Further it would have been obvious to administer a dosage which would reduce PASI by at least 50% because Leonard et al. also teaches administering the inhibitor until a meaningful patient benefit is observed by the treatment provider Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

18. Claim 38 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gillies et al. (WO 96/40093) in view of Leonard et al. (US Pat. No. 6,338,848, of record) as applied to claims 25, 34-37 and 39-42 above, and further in view of Gately et al. (US Pat. No. 6,225,117).

Claim 38 is drawn to methods of treating psoriasis by administering a monoclonal antibody that binds IL-12 and blocks its effects, wherein the antibody is monoclonal antibody 5F2, 16F2, 16G2 or 20E11 in chimeric or humanized form.

Gillies et al. in view of Leonard et al. have been discussed above.

Gillies et al. in view of Leonard et al do not teach that the anti-IL-12 antibody is 5F2, 16F2, 16G2, or 20E11.

Gately et al. teach the anti-human IL-12 monoclonal antibodies 5F2, 16F2, 16G2 and 20E11(see entire document, including claims). Gately et al. teach that the art recognized that anti-IL-12 antibodies could be used to treat several different autoimmune diseases (column 2, especially lines 6-20). Gately et al. teach that these antibodies in humanized form (see claims). Gately et al. also teach that these antibodies cross react with rhesus IL-12, making them excellent candidates for designing effective IL-12 antagonists for use in humans (column 8, especially lines 11-19), and are of higher potency than previous anti-IL-12 antibodies (column 6 at line 63 to column 7 at line 8).

The ordinary artisan at the time the invention was made would therefore have found it obvious to utilize the antibodies of Gately et al. in the method of treating psoriasis in a patient as taught by Gillies et al. in view of Leonard et al. and discussed supra. Given the teachings of the higher potency of the antibodies of Gately et al. and the fact that the antibodies could be administered to a primate prior to human therapy, the ordinary artisan would have both been motivated to utilizes the antibodies of Gately, and would have had a reasonable expectation that they could be used in a method of treating psoriasis as taught by Gillies et al. in view of Leonard et al. and discussed supra. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

19. Claims 25, 35,37 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Strober et al. (WO 98/16248, IDS) in view of Gately et al. (US Pat. No. 6,225,117).

The claims are drawn to methods of treating psoriasis by administering a monoclonal antibody that binds IL-12 and blocks its effects, including wherein the antibody is monoclonal antibody 5F2, 16F2, 16G2 or 20E11 in chimeric or humanized form.

Strober et al. have been discussed supra and teach a method of enhancing oral tolerance to treat an autoimmune disease by administering a monoclonal antibody that binds IL-12 and inhibits its effect, along with an orally administered antigen (see entire document, including claims), including the autoimmune disease psoriasis (see especially claims 11-18 and page 5 at lines 6-21).

Strober et al. do not teach that the anti-IL-12 antibody is 5F2, 16F2, 16G2, or 20E11.

Gately et al. teach the anti-human IL-12 monoclonal antibodies 5F2, 16F2, 16G2 and 20E11(see entire document, including claims). Gately et al. teach that the art recognized that anti-IL-12 antibodies could be used to treat several different autoimmune diseases (column 2, especially lines 6-20). Gately et al. teach that these antibodies in humanized form (see claims). Gately et al. also teach that these antibodies cross react with rhesus IL-12, making them excellent candidates for designing effective IL-12 antagonists for use in humans (column 8, especially lines 11-19), and are of higher potency than previous anti-IL-12 antibodies (column 6 at line 63 to column 7 at line 8).

The ordinary artisan at the time the invention was made would therefore have found it obvious to utilize the antibodies of Gately et al. in the method of treating psoriasis in a patient as taught by Strober et al. Given the teachings of the higher potency of the antibodies of Gately et al. and the fact that the antibodies could be administered to a primate prior to human therapy, the ordinary artisan would have both been motivated to utilizes the antibodies of Gately, and would have had a reasonable expectation that they could be used in a method of treating psoriasis as taught by Strober et al. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Double Patenting

20. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

21. Claims 25, 34-37 and 42 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 25-26 and 29-32 of copending Application No. 10/108,191. Although the conflicting claims are not identical, they are not patentably distinct from each other.

USSN 10/108,191 claims methods of treating psoriasis by administering an antibody, including a humanized antibody, to IL-12 (see claims 25-26, 29-32). USSN 10/108,191 claims that treating a patient with a monoclonal antibody to IL-12 that neutralizes (i.e., blocks the effect of) IL-12 reduces PASI by at least 50%. Any antibody that blocks the effect of IL-12 would inherently have an affinity of at least 10^8 M^{-1}. Thus claims 25-26 and 29-32 of USSN 10/108,191 anticipate the instant claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

22. Claims 39-41 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 25-26 and 29-32 of copending Application No. 10/108,191 in view of Leonard et al. (US Pat. No. 6,338,848, of record).

The claims are drawn to methods of treating psoriasis by administering an antibody that binds IL-12 and blocks its effects.

The claims of USSN 10/108,191 have been discussed above.

The claims of USSN 10/108,191 do not recite routes of administration, or dosages.

However, each of these limitations are obvious embodiments of any method of treating with an antibody. In particular, Leonard et al. teach methods of treating autoimmune diseases by administering antagonists of IL-12 (see entire document, e.g., Abstract). Leonard et al. teach IL-12 antagonists that are monoclonal antibodies that bind IL-12 and inhibit IL-12 activity (column 3 at line 64 to column 4 at line 37). Leonard et al. teach that the monoclonal antibodies to IL-12 can be chimeric (column 4 at lines 1-4) and formulated in pharmaceutical compositions (column 6 at lines 54-67). Leonard et al. teach that the antibodies may be administered via any of a number of routes, including by intravenous or subcutaneous injection (see column 7, especially lines 1-10). Leonard et al. also teach that administration at dosages of 0.05 mg/kg to about 25 mg/kg (see column 7, especially lines 31-34), and that the administration would continue until a meaningful patient benefit is observed by the treatment provider (column 7, lines 10-44).

In view of the teaching of Leonard et al. regarding routes of antibody administration and dosages, the ordinary artisan at the time the invention was made would have found it obvious to use anti-IL-12 antibodies in the method of treating taught in USSN 10/108,191 at any of the recited dosages and via any of the recited routes, but especially by intravenous (i.e., intravascular) or subcutaneous injection. Leonard et al teach the application of anti-IL-12 antibodies for the treatment of the class of diseases to which psoriasis may be considered to belong, i.e., autoimmune diseases; thus the ordinary artisan at the time the invention was made would have been motivated to utilize the dosing and routes of administration taught by Leonard et al. Further, given the related nature of the treatments, the ordinary artisan at the time the invention was made would have had a reasonable expectation of successfully using the dosages and routes taught by Leonard et al. for administering an anti-IL-12 antibody. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

This is a provisional obviousness-type double patenting rejection.

23 Claim 38 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 25-26 and 29-32 of copending Application No. 10/108,191 in view of Gately et al. (US Pat. No. 6,225,117).

Claim 38 is drawn to methods of treating psoriasis by administering a monoclonal antibody that binds IL-12 and blocks its effects, wherein the antibody is monoclonal antibody 5F2, 16F2, 16G2 or 20E11 in chimeric or humanized form.

The claims of USSN 10/108,191 have been discussed above.

The claims of USSN 10/108,191 do not recite that the anti-IL-12 antibody is 5F2, 16F2, 16G2, or 20E11.

Gately et al. teach the anti-human IL-12 monoclonal antibodies 5F2, 16F2, 16G2 and 20E11(see entire document, including claims). Gately et al. teach that the art recognized that anti-IL-12 antibodies could be used to treat several different autoimmune diseases (column 2, especially lines 6-20). Gately et al. teach that these antibodies in humanized form (see claims). Gately et al. also teach that these antibodies cross react with rhesus IL-12, making them excellent candidates for designing effective IL-12 antagonists for use in humans (column 8, especially lines 11-19), and are of higher potency than previous anti-IL-12 antibodies (column 6 at line 63 to column 7 at line 8).

The ordinary artisan at the time the invention was made would therefore have found it obvious to utilize the antibodies of Gately et al. in the method of treating psoriasis in a patient as claimed in USSN 10/108,191. Given the teachings of the higher potency of the antibodies of Gately et al. and the fact that the antibodies could be administered to a primate prior to human therapy, the ordinary artisan would have both been motivated to utilizes the antibodies of Gately, and would have had a reasonable expectation that they could be used in the method of USSN 10/108,191. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

This is a provisional obviousness-type double patenting rejection.

Conclusion

24. No claim is allowed.

25. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jessica Roark, whose telephone number is (703) 605-1209. The examiner can normally be reached Monday to Friday from 8:00 to 4:30. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached at (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number for before Final submissions is (703) 872-9306.

Jessica Roark, Ph.D.
Patent Examiner
Technology Center 1600
November 12, 2003

PHILLIP GAMBEL
PHILLIP GAMBEL, PH.D
PRIMARY EXAMINER
TECH CENTER 1600
11/12/03